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10/530,411	04/07/2005	Toru Eguchi	050224	5782

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EXAMINER

PANI, JOHN

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3709

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,411	Applicant(s) EGUCHI ET AL.	
	Examiner John Pani	Art Unit 3709	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/07/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>04/07/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 10 and 19 objected to because of the following informalities:

In line 2 of claim 10, and line 2 of claim 19, it is suggested to replace "bottomed-cylindrical" with --cylindrically bottomed--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless --(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 6, 7, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0520408 to Seymour (Seymour).

Seymour teaches:

In reference to Claim 1

A sputum collecting tool comprising: a sputum-collecting device (**sample collector 2113**) in which a handle part (**push tab 2120**) is disposed on one end of a base part (**elongated member 2116**) which has a sputum-collecting part (**2115 and filter paper 2117**) that collects sputum attached to the other end (**See Fig. 28**); and a collection sample container (**sample container 2111**) for accommodating this sputum-collecting device therein (**See Fig. 50**); and

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characterized in that grip faces that are positioned on both ends of said handle part in a thickness direction are formed substantially flat (**The surface of 2120 facing outward in Fig. 28 is flat other than the protrusion in the center**), and the left-right width dimension of said handle part (**2120**) is set greater than the left-right width dimension of said base part (**2116**) (**See Fig. 28**).

In reference to Claim 2

The sputum-collecting tool according to claim 1 (**See rejection of claim 1 by Seymour**), wherein recesses or protrusions (**A protrusion is formed in the center of 2120 on both sides of the device**), or both, are formed in substantially the central portions of said grip faces.

In reference to Claim 3

The sputum-collecting tool according to claim 1 (**See rejection of claim 1 by Seymour**), comprising a stopper (**See the disc that sits perpendicular to the long axis of 2116 at point 2118 in Fig. 28**) on the base part end portion of said handle part (**2120**) which prevents the fingers grasping said handle part (**2120**) from moving toward the base part (**2116**) by contacting said fingers (**This structure would fulfill this purpose**).

In reference to Claim 4

The sputum-collecting tool according to claim 1 (**See rejection of claim 1 by Seymour**), wherein a fiber bundle (**filter paper 2117**) formed by bundling a plurality of fiber (**See MPEP § 2113 regarding product-by-process claims**) for sucking up the sputum collected by said sputum-collecting part is disposed on said base part (**2116**), and an intermediate portion of this fiber bundle is colored

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with a coloring agent that can be dispersed by the sputum (**See col. 12 lines 12-20**).

In reference to Claim 6

The sputum-collecting tool according to claim 1 (**See rejection of claim 1 by Seymour**), wherein a flange part (**See the disc that sits perpendicular to the long axis of 2116 at point 2118 in Fig. 28**) for placing said collection sample container (**2111**) in a tightly closed state by engaging with the inner surface of said collection sample container (**2111**) when the insertion of said sputum-collecting device (**2113**) into said collection sample container (**2111**) is completed is disposed between the handle part (**2120**) and base part (**2116**) of said sputum-collecting device (**2113**) (**See Fig. 50, the protruding disc tightly contacts the inner wall of 2111 when 2113 is placed inside 2111**).

In reference to Claim 7

The sputum-collecting tool according to claim 1 (**See rejection of claim 1 by Seymour**), wherein at least a portion of the handle part (**2120**) of said sputum-collecting device (**2113**) is covered by the container main body of said collection sample container (**2111**) in a state in which the insertion of said sputum-collecting device into said collection sample container is completed (**See Fig. 50**).

In reference to Claim 9

The sputum-collecting tool according to claim 1 (**See rejection of claim 1 by Seymour**), wherein the handle part (**2120**) of said sputum-collecting device (**2113**) is disposed (**2120 is coupled to 2116**) in the base part (**2116**) of said

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sputum-collecting device (2113) so that said handle part (2120) can be separated **(2120 could be separated from 2116 in a variety of ways, for example, by breaking or cutting 2116 below point 2118)** from said base part (2116) as said handle part is pulled out in order to remove said sputum-collecting device (2113) from said collection sample container (2111) in a state in which said sputum-collecting device (2113) is inserted into and accommodated in said collection sample container (2111) **(2120 can be inserted into or pulled out from 2111, see Figs 28 and 50).**

In reference to Claim 10

Seymour teaches a sputum-collecting tool according to claim 1 (**See rejection of claim 1 by Seymour**), and further teaches said collection sample container (2111) comprises a bottomed-cylindrical lower part (**section of 2111 below narrowing at center of 2111 shown in Fig. 31**) which accommodates (**See Fig. 55**) the base part (2116) of said sputum-collecting device (2113), and an upper part (**section of 2111 above narrowing at center of 2111 shown in Fig. 31**) which is integrally connected with the upper end portion of this lower part (**See Fig. 31**), and which is constructed with a size so as to cover at least a portion of the handle part (2120) of said sputum-collecting device (2113) from the outside (**See Fig. 55**), in which a cut part (**the narrowing at center of 2111 shown at center of 2111 in Fig. 2111**) is provided which allows said lower part and upper part to be cut apart in the connecting portion of said both parts (**The narrowing would allow for one to cut apart the top and bottom portions of 2111, for example by running a blade around it**).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seymour in view of US Pat. No. 5,882,942 to Kagaya (Kagaya) *of record*¹².

In reference to Claim 5

Seymour teaches a sputum-collecting tool according to claim 1 (**See rejection of claim 1 by Seymour**), wherein said collection sample container (2111) comprises a container main body (2111) which is equipped at one end thereof with a removal piece (**breakable seal 2125**) that can be cut away (**If 2125 can be broken, it can also be cut away**) to allow removal of an internal accumulated liquid (**See col. 14 lines 23-28**), and a freely detachable closing cap (**cap 2112**) for closing off an opening part (2123) formed in the other end of this container main body (2111) (**See Fig. 31**). However, Seymour does not teach that the removable piece forms a projection protruding to the outside.

Kagaya teaches of a device for sampling feces that includes a collecting stick 15 and a container 13 that accommodates a liquid. The device includes a dripping portion 11 and a leg 23 protruding to the outside of the device (**See Fig.**

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1) to allow for removal of accumulated internal liquid (**col. 4 lines 15-23**).

Additionally, a notch **28** is included to allow for **23** to be easily broken open.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have replaced the flat, breakable seal **2125** in the device taught by Seymour with the dripping portion **11**, leg **23**, and notch **28** taught by Kagaya because it would allow one to remove accumulated fluid from the device taught by Seymour without requiring an additional piece to puncture the seal.

In reference to Claim 8

Seymour in view of Kagaya teaches a sputum-collecting tool according to claim 5 (**See rejection of claim 5 by Seymour in view of Kagaya**), and Kagaya further teaches a leg part (**23**) that would be capable of making the collection sample container (**13**) self stand. The leg part (**23**) is disposed on the removable piece (**part of 11 below 28**) of the collection sample container (**13**). (**The leg part 23 is flat on its bottom, and would be capable of holding the device upright.**)

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seymour in view of WO 94/04078 to Thieme et al. (Thieme) *of record*^{TL}.

Seymour teaches a sputum-collecting tool according to claim 1 (**See rejection of claim 1 by Seymour**) but does not teach that the said sputum-collecting part is made of polyurethane.

Thieme teaches an oral fluid collection device **8** that includes a pad **10** for collecting oral fluids. Thieme teaches that the pad **10** can be made from

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absorbent materials suitable for oral use, including polyurethane (**page 6 line 33 – page 7 line 5**).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the invention taught by Seymour by substituting a polyurethane structure for the filter paper structure **2117** because polyurethane is an absorbent material suitable for oral use, as explicitly taught by Thieme.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seymour in view of JP 10-96725 to Taizo et al. (Taizo) *of record*. ^{PL}.

Seymour teaches a sputum-collecting tool according to claim 1 (**See rejection of claim 1 by Seymour**) but does not teach that the said sputum-collecting part is made of cellulose acetate.

Taizo teaches a device for detecting the existence of specific components found in biological liquids such as saliva (**[0001]**). The device consists of a handle **3** and a wick **2** that contacts the sampled bodily fluid. Thieme also teaches that the wick be preferably made from a porous organic body such as cellulose acetate (**[0018-0019]**).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the invention taught by Seymour by substituting a cellulose acetate structure for filter paper structure **2117** because cellulose acetate is a porous organic body suitable for absorbing bodily fluids, as taught by Taizo.

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8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seymour in view of JP 2001-033359 to Soichi et al. (Soichi) *of record. TL*

Seymour teaches the sputum-collecting tool according to claim 1 (**See rejection of claim 1 by Seymour**) but does not teach that the said collection sample container is set at 10mm or less, nor mention the size at all.

Soichi teaches of a device for extracting sputum and other bodily fluids ([0001]), and further teaches that the exterior tubing should preferably be 10mm in diameter or less so that the device could be mailed in an envelope ([0007]).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device taught by Seymour so that the sampling container had a thickness 10mm or less so that the device could be mailed in an envelope as explicitly taught by Soichi.

9. Claim 14 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seymour in view of US Pat. No. 4,221,295 to Tuchband et al. (Tuchband).

In reference to Claim 14

Seymour teaches a sputum-collecting tool as claimed (**See rejection of claim 1 by Seymour**), but does not mention a box form casing main body accommodating the tool, or a cover body attached to the casing main body which can be freely opened and closed by swinging in order to close off the open side of the casing main body.

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Tuchband teaches of a urine collection device and a package for that device that includes a box form casing main body (2) accommodating a tool, and a cover (6) that can be opened and closed by swinging. The package is intended to ship the device in a sterile condition (**col. 1 lines 40-45**).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have included a package with a main body and a cover, as taught by Tuchband, to enclose the device taught by Seymour, so that the device could be shipped in a sterile condition, as explicitly taught by Tuchband.

In reference to Claim 16

Seymour in view of Tuchband teaches a sputum-collecting tool kit according to claim 14 (**See rejection of claim 14 by Seymour in view of Tuchband**), and Tuchband further teaches a diagram explaining use is printed on the inside surface of the cover body (**See col. 3 lines 50-59**).

In reference to Claim 17

Seymour in view of Tuchband teaches a sputum-collecting tool kit according to claim 14 (**See rejection of claim 14 by Seymour in view of Tuchband**), and Tuchband further teaches an accommodating part that can accommodate a mailing envelope in said cover body (**See Fig. 5, The cover accommodates several packets of sanitary towelettes, and could therefore accommodate a mailing envelope**).

In reference to Claim 18

Seymour in view of Tuchband teaches a sputum-collecting tool kit according to claim 14 (**See rejection of claim 14 by Seymour in view of**

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Tuchband), and Seymour further teaches sputum-collecting tool according to claim 1 (**See rejection of claim 1 by Seymour**), wherein the handle part (2120) of said sputum-collecting device (2113) is disposed (**2120 is coupled to 2116**) in the base part (2116) of said sputum-collecting device (2113) so that said handle part (2120) can be separated (**2120 could be separated from 2116 in a variety of ways, for example, by breaking or cutting 2116 below point 2118**) from said base part (2116) as said handle part is pulled out in order to remove said sputum-collecting device (2113) from said collection sample container (2111) in a state in which said sputum-collecting device (2113) is inserted into and accommodated in said collection sample container (2111) (**2120 can be inserted into or pulled out from 2111, see Figs 28 and 50**).

In reference to Claim 19

Seymour in view of Tuchband teaches a sputum-collecting tool kit according to claim 14 (**See rejection of claim 14 by Seymour in view of Tuchband**), and Seymour further teaches a sputum-collecting tool according to claim 1 (**See rejection of claim 1 by Seymour**), and further teaches said collection sample container (2111) comprises a bottomed-cylindrical lower part (**section of 2111 below narrowing at center of 2111 shown in Fig. 31**) which accommodates (**See Fig. 55**) the base part (2116) of said sputum-collecting device (2113), and an upper part (**section of 2111 above narrowing at center of 2111 shown in Fig. 31**) which is integrally connected with the upper end portion of this lower part (**See Fig. 31**), and which is constructed with a size so as to cover at least a portion of the handle part (2120) of said sputum-collecting

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device (2113) from the outside (**See Fig. 55**), in which a cut part (**the narrowing at center of 2111 shown at center of 2111 in Fig. 2111**) is provided which allows said lower part and upper part to be cut apart in the connecting portion of said both parts (**The narrowing would allow for one to cut apart the top and bottom portions of 2111, for example by running a blade around it**).

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seymour : *and* Tuchband as applied to claim 14 above, and further in view of US Pat. No. 5,786,228 to Charlton (Charlton).

Seymour in view of Tuchband teaches a sputum-collecting tool kit according to claim 14 (**See rejection of claim 14 by Seymour in view of Tuchband**) but does not teach a holding part for holding the collection sample container in an upright attitude.

Charlton teaches of a fluid collection kit that includes a container 39 for holding tubes and caps in a readily accessible, upright manner (**See col. 5 lines 35-48**).

It would have been obvious to one having ordinary skill in the art to have (when providing a package taught by Tuchband to contain the device taught by Seymour) altered the cavities taught by Tuchband so that they were optimally shaped to hold the device taught by Seymour, particularly by making the cavities long cylinders so as to hold the tubes in a readily accessible manner as taught by Charlton.

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11. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seymour *and* Tuchband as applied to claim 14 above, and further in view of Thieme.

Seymour in view of Tuchband teaches a sputum-collecting tool kit according to claim 14 (**See rejection of claim 14 by Seymour in view of Tuchband**), but does not teach that the sputum-collecting part is made of polyurethane.

Thieme teaches an oral fluid collection device **8** that includes a pad **10** for collecting oral fluids. Thieme teaches that the pad **10** can be made from absorbent materials suitable for oral use, including polyurethane (**page 6 line 33 – page 7 line 5**).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the invention taught by Seymour by substituting a polyurethane structure for the filter paper structure **2117** because polyurethane is an absorbent material suitable for oral use, as explicitly taught by Thieme.

12. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seymour *and* Tuchband as applied to claim 14 above, and further in view of Taizog *re cord* ¹¹.

Seymour in view of Tuchband teaches a sputum-collecting tool kit according to claim 14 (**See rejection of claim 14 by Seymour in view of**

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Tuchband), but does not teach that the sputum-collecting part is made of cellulose acetate.

Taizo teaches a device for detecting the existence of specific components found in biological liquids such as saliva ([0001]). The device consists of a handle 3 and a wick 2 that contacts the sampled bodily fluid. Thieme also teaches that the wick be preferably made from a porous organic body such as cellulose acetate ([0018-0019]).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the invention taught by Seymour by substituting a cellulose acetate structure for filter paper structure 2117 because cellulose acetate is a porous organic body suitable for absorbing bodily fluids, as taught by Taizo.

13. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seymour *and* Tuchband as applied to claim 14 above, and further in view of Soichi *of record*. ¹²

Seymour in view of Tuchband teaches a sputum-collecting tool kit according to claim 14 (**See rejection of claim 14 by Seymour in view of Tuchband**), but does not teach that thickness of the collection sample container is set at 10 mm or less.

Soichi teaches of a device for extracting sputum and other bodily fluids ([0001]), and further teaches that the exterior tubing should preferably be 10mm in diameter or less so that the device could be mailed in an envelope ([0007]).

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It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device taught by Seymour so that the sampling container had a thickness 10mm or less so that the device could be mailed in an envelope as explicitly taught by Soichi.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 2003/0045814 to Sangha discloses a DNA collection device with a removable handle.

US 2003/0064526 to Niedbala et al. discloses a sample collector with a removable handle.

US Pat. No. 5,070,884 to Columbus et al. discloses a sampling syringe with a removable handle.

US Pat. No. 4,777,964 to Briggs et al. discloses an HIV sampling kit that includes an envelope for sending the sample to a laboratory.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Pani whose telephone number is 571-270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

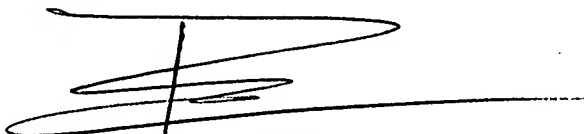
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kenneth Bomberg can be reached on 571-272-4922. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 6/13/07

A handwritten signature in black ink, consisting of a stylized 'T' and 'L' with a vertical line through the middle, followed by a horizontal line.

THAO X. LE
PRIMARY PATENT EXAMINER